Ignore this ref to a wrong application NO.
MMR 9/26/03

REMARKS/ARGUMENTS

Specification

The substituted paragraphs beginning on pages 34, 38, 76, 81, 105, 113, and 114 were amended merely to add SEQ ID NOS in compliance with 37 CFR § 1.821 (d).

The substituted paragraph on page 62 was amended merely to delete a typographical error.

No new matter has been added by way of these amendments to the specification.

Claims

Claims 1-2, 6-20 are currently pending. Claims 3-5 have been canceled. Claims 21-55 have been withdrawn as directed to a non-elected invention. Claims 56-63 have been added. Claims 1, 2, 6 and 7 have been amended.

Claim 1 has been amended to recite a polynucleotide having ABC1 promoter activity. Claim 2 has been amended to recite a polynucleotide having ABC1 promoter activity and to delete reference to nucleotide sequence 1394-1592. Claim 6 has been amended to recite an isolated polynucleotide having ABC1 promoter activity that is at least 80% identical to SEQ ID NO: 3. Claim 7 has been amended to recite an isolated polynucleotide having ABC1 promoter activity that is at least 80% identical to nucleotides 1-1532, 1080-1643, 1181-1643, 1292-1643, 1394-1643, or 1394-1532 of SEQ ID NO: 3. New claim 56 is directed to an isolated polynucleotide comprising the polynucleotide of claim 6. New claim 57 is directed to an isolated polynucleotide comprising the polynucleotide of claim 7. Support for all of these amendments can be found throughout the specification, for example, at pages 8-9, 27, 37-39, 47-49, and 108-116.

New claim 58 is directed to a recombinant vector comprising the polynucleotide of claim 56. New claim 58 is directed to a recombinant vector comprising the polynucleotide of claim 57. Support for these amendments can be found throughout the specification, for example, at pages 11-12, and 46-49.

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New claims 60 and 61 are directed to an isolated polynucleotide consisting essentially of nucleotides1394-1532 of SEQ ID NO: 3 and a recombinant vector comprising said polynucleotide, respectively. Support for the amendments can be found throughout the specification, for example, at pages 8-9, 11-12, 37-39, and 46-49.

New claim 62 is directed to an isolated polynucleotide that is at least 91% identical to the polynucleotide of SEQ ID NO: 3. New claim 63 is directed to an isolated polynucleotide that is at least 90% identical to nucleotides 1-1532, 1080-1643, 1181-1643, 1292-1643, 1394-1643, or 1394-1532 of SEQ ID NO: 3. Support for the amendments can be found throughout the specification, for example, at pages 8-9 and 37-39.

Discussion of the 35 U.S.C. § 112 Rejections

Enablement

Claims 4-7 were rejected under 35 USC § 112, first paragraph, as allegedly not enabled. Applicants respectfully traverse the rejection.

The Office alleges that while the specification is enabling for a polynucleptide comprising SEQ ID NO: 3 and polynucleotides comprising specific fragments of SEQ ID NO: 3, it does not provide enablement for any polynucleotides comprising a sequence that hybridizes to SEQ ID NO: 3 or its specific fragments or any polynucleotides that are at least 80% identical to SEQ ID NO: 3 or its specific fragments. With respect to claims 4 and 5, without conceding to the merits of the allegation, claims 4 and 5 have been canceled, rendering the rejection moot.

Under 35 U. S. C. § 112, all that is required is that the specification describe the invention in such terms as to enable a person skilled in the art to make and use the invention. Thus, with respect to claims 6 and 7, the specification must teach one skilled in the art how to make and use a polynucleotide having ABC1 promoter activity that is at least 80% identical to SEQ ID NO: 3 or nucleotides 1-1532, 1080-1643, 1181-1643, 1292-1643, 1394-1643, and 1394-1532 of SEQ ID NO: 3. The test of enablement is whether one reasonably skilled in the art (1) could make

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and use the invention (2) from the disclosures in the patent coupled with information known in the art (3) without undue experimentation. *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988); *United States v. Telectronics, Inc.*, 857 F.2d 778 (Fed. Cir. 1988); M.P.E.P. § 2164.01.

Contrary to the Office's allegation, the instant specification provides considerable guidance to enable a skilled artisan to make and use a polynucleotide having promoter activity that is at least 80% identical to SEQ ID NO: 3 or nucleotides 1-1532, 1080-1643, 1181-1643, 1292-1643, 1394-1643, and 1394-1532 of SEQ ID NO: 3. For example, the instant specification teaches that the polynucleotides can be produced chemically, enzymatically, or metabolically (specification at page 22) and provides examples of polynucleotide variants having biological activity, including those having additions, deletions, and silent substitutions, such as those due to degeneracy of the code (specification at page 27 and 39). The specification further provides a detailed description of the recombinant methods and techniques used to produce the polynucleotides of the invention, including making and amplifying the polynucleotides (specification at, for example, page 95-98, 101-102, 108-109, and 112-116). The specification further teaches the sequencing of the polynucleotides and how to determine the % identity with SEQ ID NO: 3 or a fragment thereof (specification at, for example, pages 95-98 and 24-26). While the recombinant techniques described throughout the specification and particularly in Examples 15-18 were used to produce *exemplary polynucleotides* corresponding to SEQ ID NO: 1, SEQ ID NO: 3 and nucleotides 1-1532, 1080-1643, 1181-1643, 1292-1643, 1394-1643, and 1394-1532 of SEQ ID NO: 3, these same techniques and other standard recombinant techniques widely known in the art and easily within the skill of the ordinary artisan can be used to produce additional polynucleotides having at least 80% identity to SEQ ID NO: 3 or nucleotides 1-1532, 1080-1643, 1181-1643, 1292-1643, 1394-1643, and 1394-1532 of SEQ ID NO: 3.

Further, the specification provides a detailed description of the methods used to test the claimed polynucleotides for promoter activity, including the construction of reporter vectors,

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transfection into host cells and reporter assays (specification at pages 14-15, 41-51, 55-60, 75-78, and Examples 15-18).

The Office alleges that the scope of the claims are not commensurate with the enablement provided by the disclosure because the claims encompass an enormous number of polynucleotide sequences. Further, the Office alleges that while recombinant and mutagenesis techniques are known, it is not routine to screen for substitutions or modifications of nucleotides and given that the results of such changes are unpredictable, the reasonable expectation of success in obtaining the desired activity (i.e., promoter activity) is limited. First, given that the claims are limited to those polynucleotide sequences that have ABC1 promoter activity, they do not encompass an infinite number of polynucleotides as the Office suggests. In addition, as discussed above, the specification teaches one skilled in the art how to produce the polynucleotides of the invention using well-established and standard recombinant techniques that are well within the knowledge and skill of the ordinary artisan. Applicant submits that it is routine experimentation to use recombinant, mutagenesis, amplification, and sequencing techniques to make and determine the sequences of variant polynucleotides. Applicant further submits that it is a matter of routine experimentation to screen variant nucleotide sequences for promoter activity using the techniques described in the specification and other well-known techniques. The law clearly states that "a considerable amount of experimentation is permissible, if it is merely routine." *In re Wands,* 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988). Further, the fact that experimentation may be complex does not necessarily make it undue. *Massachusetts Institute of Technology v. A.B. Fortia,* 774 F.2d 1104 (Fed. Cir. 1985); *In re Wands,* 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988). Thus, the test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 537 F.2d 498 (CCPA 1976). Applicant submits that such routine work as producing variant polynucleotides and screening them to determine activity is well within the knowledge and skill of the ordinary artisan and does not involve undue experimentation.

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The Office further alleges that the specification does not support the broad scope of the claims because the specification does not establish regions of the polynucleotide sequence that can be modified without affecting activity, the general tolerance of the ABC1 promoter sequence to modification, and a rational and predictable scheme for modifying the promoter sequence with the expectation of obtaining the desired activity. However, in contrast to the Office's allegation, the specification establishes regions of the polynucleotide sequence that can not be modified without affecting activity by teaching the sequence and position of several transcription regulatory elements, including a TATA box, several transcription factor binding sites, such as SP1 sites, several nuclear receptor half sites, and sterol response element sites (specification at page 38, Figure 13). One skilled in the art would realize that these sites, as well as other known and published consensus sites, would tolerate limited modification, if any. In addition, the reporter assay studies in Example 18 provide additional guidance into which sequences can be modified without affecting promoter activity. For example, Example 18 establishes that nucleotides 1394-1643 retain promoter activity, indicating that certain sequences upstream of nucleotide 1394 can tolerate modification and retain activity. In view of the sites mapped and disclosed in SEQ ID NO: 3, as well as in view of other known and published consensus sequences, one skilled in the art would realize which areas and sequences of the promoter region could be modified without abolishing promoter activity.

For the reasons discussed above, the claims are fully enabled by the specification. Accordingly, the Applicants respectfully requests withdrawal of the 35 U.S.C. § 112 rejections.

Written Description

Claims 1-20 were rejected under 35 USC § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s) had possession of the claimed invention at the time the application was filed. Applicants respectfully traverse the rejection.

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To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art could reasonably conclude that the inventor had possession of the claimed invention. *See, e.g., id.* at 1116; M.P.E.P § 2163(I). There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. M.P.E.P. § 2163(I)(A) (citing *In re Wertheim*, 541 F.2d 257, 263, 191 U.S.P.Q. 90, 97 (C.C.P.A. 1976)). Thus, a description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. *See, e.g., In re Marzocchi*, 169 U.S.P.Q. 367, 370 (C.C.P.A. 1971); M.P.E.P. § 2163.04. Therefore, the Office must have a reasonable basis to challenge the adequacy of the written description and has the initial burden of presenting, by a preponderance of the evidence, why a person skilled in the art would not recognize in an Applicant's disclosure a description of the invention defined by the claims. *See, e.g., In re Wertheim*, 191 U.S.P.Q. 90, 97 (C.C.P.A. 1976); *Ex parte Sorenson*, 3 USPQ2d 1462 (Bd. Pat. App. & Int. 1987); M.P.E.P. § 2163.04.

Whether the specification shows that an applicant was in possession of the claimed invention is a factual determination. M.P.E.P. § 2163(I). Possession is shown "by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention." M.P.E.P. § 2163.02 (citing *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997)). Factors to be considered in determining whether there is sufficient evidence of possession include: (1) the level of skill and knowledge in the art; (2) partial structure; (3) physical and/or chemical properties; (4) functional characteristics alone or coupled with a known or disclosed correlation between structure and function; (5) and the method of making the claimed invention. *Id.* at (II)(A)(2)-(3)(a). Disclosure of *any* combination of such identifying characteristics that distinguish the claimed invention such that one skilled in the art would conclude that the applicant was in possession of the claimed species is sufficient to satisfy written description. *Id*;

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see Reagents of the Univ. of Calif. v. Eli Lilly, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406. Correspondingly, as the Patent Office's internal guidelines assert, "the written description requirement may be satisfied through disclosure of function and minimal structure when there is a well-established correlation between structure and function." M.P.E.P. § 2163(II)(A)(3)(a)(i)(C)(2). Thus, when "knowledge and level of skill in the art is high, a written description question *should not be raised* for original claims even if the specification discloses only a method of making the invention and the function of the invention." *Id.* (emphasis added), *see In re Hayes Microcomputer Products, Inc. Patent Litigation*, 982 F.2d 1527, 1534-35, 25 U.S.P.Q.2d 1241, 1246 (Fed. Cir. 1992) ("An applicant's disclosure obligation varies according to the art to which the invention pertains.").

Moreover, that which is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. M.P.E.P. § 2163 (citing *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986)). Further, the written description requirement does not require an actual reduction to practice. M.P.E.P. § 2163. Accordingly, an Applicant need not show that the invention will work for its intended purpose to satisfy the written description requirement.

The Office alleges that the specification does not contain any disclosure and function of all of the DNA sequences that are encompassed in the genus of DNA molecules comprising either SEQ ID NO: 3, fragments of SEQ ID NO: 3, or polynucleotides that are 80% identical to SEQ ID NO: 3 or fragments thereof. Without conceding to the merits of the allegation, claims 3- 5 have been canceled, rendering the rejection moot as to these claims.

With respect to claims 1, 2, 6, and 7, contrary to the Office's allegation, the specification thoroughly describes an isolated polynucleotide having ABC1 promoter activity comprising SEQ ID NO: 3 and an isolated polynucleotide having ABC1 promoter activity comprising nucleotides 1-1532, 1080-1643, 1181-1643, 1292-1643, or 1394-1643 of SEQ ID NO: 3. As discussed herein, evidence of possession is demonstrated by the description of several factors listed in M.P.E.P. § 2163.02 as identifying characteristics that distinguish the claimed invention. The claims are limited

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to those polynucleotides containing the nucleotide sequence of SEQ ID NO. 3, or a specified fragment thereof, and having ABC1 promoter activity. The specification clearly teaches the structure of the claimed polynucleotide in providing the 1643 bp nucleotide sequence of SEQ ID NO: 3, and the nucleotide sequence of nucleotides 1-1532, 1080-1643, 1181-1643, 1292-1643, 1394-1643, or 1394-1532 of SEQ ID NO: 3. The specification also clearly teaches the ABC1 promoter function of the claimed polynucleotides and provides demonstration of ABC1 promoter activity in Examples 15-18. In addition, the specification clearly teaches the structure and function of an isolated polynucleotide having ABC1 promoter activity that is at least 80% identical to SEQ ID NO: 3 and nucleotides 1-1532, 1080-1643, 1181-1643, 1292-1643, 1394-1643, or 1394-1532 of SEQ ID NO: 3 (see above discussion of the teaching for claims 6 and 7). With respect to claims 8 and 9, one skilled in the art would know the nucleotide sequence of a polynucleotide that is complementary to SEQ ID NO: 3 or the specified fragments thereof.

The Office alleges that the specification does not disclose a representative number of species in the claimed genus. However, the specification describes and provides several examples of the claimed polynucleotides. For example, the specification teaches and provides numerous examples of polynucleotides having ABC1 promoter activity comprising SEQ ID NO: 3 (and heterologous polynucleotides) in the specification at pages 46-49, 76, Example 4, and Example 15. The specification further provides a diagram of an exemplary polynucleotide in Figure 11. The specification also teaches and provides examples of polynucleotides having ABC1 promoter activity comprising nucleotides 1-1532, 1080-1643, 1181-1643, 1292-1643, 1394-1643, or 1394-1532 of SEQ ID NO: 3 in Example 18, SEQ ID NO: 1 and Figure 4.

In addition to teaching the structure and function of the claimed polynucleotides, the specification also contains a thorough description of how to make and test the claimed polynucleotides for ABC1 promoter activity. For example, the specification teaches how to make the claimed polynucleotides at pages 46-49, 76, and Examples 15-18. The specification teaches how to test the claimed polynucleotides for ABC1 promoter activity at pages 75-77,

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Example 4, and Examples15-18. Using these techniques and other techniques well-known in the art, one skilled in the art could easily make additional polynucleotides having ABC1 promoter activity and comprising SEQ ID NO: 3, or a specified fragment thereof.

With respect to claims 11 and 12, the specification clearly teaches compositions comprising the claimed polynucleotides at pages 40-41, 60-62 and 68. With respect to claims 12, 13, 16-20, the specification clearly teaches recombinant vectors comprising the claimed polynucleotides (and heterologous polynucleotides) and provides numerous examples of suitable vectors, as well as heterologous polynucleotides at pages 41-49, 75-77, Example 4, and Examples 15-18. The specification further provides a diagram of an exemplary vector in Figure 11 (vector in claim 20). The specification also teaches methods for making the claimed vectors at pages 41-49, 75-77, Example 4, and Examples 15-18. With respect to claims 14 and 15, the specification clearly teaches host cells comprising the claimed polynucleotides at pages 50, 76, Example 4, and Examples 15-18. The specification further teaches methods of administrating the claimed polynucleotides to host cells at pages 53-60 and 63-68.

Finally, the specification teaches a correlation between ABC1 promoter sequence and activity by teaching the sequence and position of several transcription regulatory elements, including a TATA box, several transcription factor binding sites, such as SP1 sites, several nuclear receptor half sites, and sterol response element sites (specification at page 38, Figure 13).

Based on the teachings in the specification of the structure of the claimed polynucleotides, its functional characteristics, the correlation between its structure and function, and the methods of making the claimed polynucleotide molecules, as outlined above, Applicant has clearly described identifying characteristics that distinguish the claimed polynucleotide molecules, such that one skilled in the art would conclude that Applicant was in possession of the claimed invention.

For the reasons discussed above, the claims satisfy the written description requirement. Accordingly, the Applicants respectfully requests withdrawal of the 35 U.S.C. § 112 rejections.

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Discussion of the 35 U.S.C. § 102 Rejections

35 U.S.C. § 102(a) Rejection

The Office rejected claim 3 under 35 U.S.C. § 102(a) as allegedly being anticipated by Birren et al. (GenBank Accession No.AC012230, April 22, 2000). The rejection is respectfully traversed.

The Office alleges that Birren et al. anticipates claim 3 because it discloses a polynucleotide comprising nucleotides 1394-1532 of SEQ ID NO. 3. Without conceding to the merits of the allegation, claim 3 has been canceled, rendering the rejection moot.

Accordingly, Applicant respectfully requests withdrawal of the 35 U.S.C. § 102(a) rejection in view of the Birren reference.

Applicant notes that new claims 60 and 61 are directed to an isolated polynucleotide that consists essentially of nucleotides 1394-1532 of SEQ ID NO: 3 and a recombinant vector thereof, respectively. The 1394-1532 nucleotide fragment is 138 nucleotides in length. In contrast, Birren et al. discloses a contig sequence that is 1681 nucleotides in length (nucleotides 2735-4415). Accordingly, Birren et al. does not disclose an isolated polynucleotide that consist essentially of nucleotides 1394-1532 of SEQ ID NO: 3.

35 U.S.C. § 102(b) Rejection

The Office rejected claims 4 and 5 under 35 U.S.C. § 102(b) as allegedly being anticipated by NCI-CGAP (GenBank Accession No.AA527406, August 21, 1997). The Office alleges that NCI-CGAP anticipates claims 4-5 because it discloses a polynucleotide that is 99.1% identical to a stretch of SEQ ID NO: 3 and is therefore capable of hybrizing under stringent conditions. Without conceding to the merits of the allegation, claims 4 and 5 have been canceled, rendering the rejection moot.

Accordingly, Applicant respectfully requests withdrawal of the 35 U.S.C. § 102(b) rejection in view of the NCI-CGAP reference.

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35 U.S.C. § 102(e) Rejection

The Office rejected claims 4-7 under 35 U.S.C. § 102(e) as allegedly being anticipated by Rosier-Montus (WO 01/83746; GenBank Accession Nos. AX351029 and AX351031). The Office alleges that Rosier-Montus anticipates claims 4-7 because it discloses a polynucleotide that is 89% or 90% identical to SEQ ID NO:3 and nucleotides 1-1532 of SEQ ID NO:3, respectively, and is therefore capable of hybrizing under stringent conditions to the claimed molecules. Without conceding to the merits of the allegation, claims 4 and 5 have been canceled, rendering the rejection moot.

Under 35 U.S.C. § 102(e), a claim is anticipated only if each and every element as set forth in the claim is found in a single art reference. *Verdegaal Bros. v. Union Oil Co.*, 814 F.2d 628, 631, 2 USPQ2d 1051, 10533 (Fed. Cir. 1987); *In re Recombinant DNA Technology Patent and Contract Litigation*, 30 USPQ2d 1881 (S.D. Ind.1993) ("A patent is anticipated only if all the elements and limitations of the claims are found within a single, prior art reference."); *Structural Rubber Products Co. v. Park Rubber Co.*, 749 F.2d 707, 716 (Fed. Cir. 1984) (All elements of the claimed invention must be contained in a single prior art disclosure and must be arranged in the prior art disclosure as in the claimed invention); M.P.E.P § 2131. Furthermore, no difference may exist between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of invention. *In re Recombinant DNA Technology Patent and Contract Litigation*, 30 USPQ2d 1881 (S.D. Ind.1993). Also, the identical invention must be described or shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); *Chester v. Miller*, 15 USPQ2d 1333 (Fed. Cir. 1990); M.P.E.P. § 2131.

Claim 6 as amended is directed to an isolated polynucleotide that is at least 80% identical to SEQ ID NO: 3 (nucleotides 1-1643). Rosier-Montus discloses a 3231 bp polynucleotide (sequence 1 in WO 0183746) having some sequence identity with SEQ ID NO: 3. However, assuming 100% sequence identity with nucleotides 1-1643, a polynucleotide sequence that is

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3231 bp in length (i.e., sequence 1 in WO 0183746) has, at best, only 50.8% identity with SEQ ID NO: 3. Thus, the 3231 bp polynucleotide disclosed in Rosier-Montus is not an isolated polynucleotide that is at least 80% identical to SEQ ID NO: 3, as required by claim 6. Given that the 3231 bp sequence taught in Rosier-Montus does not teach each and every element as set forth in the claim, it does not anticipate claim 6.

Claim 7 has been amended to recite an isolated polynucleotide that is at least 80% identical to, among other sequences, nucleotides 1-1532 of SEQ ID NO: 3. Rosier-Montus discloses a 2893 bp polynucleotide (sequence 3 in WO 0183746) having some sequence identity with nucleotides 1-1532 of SEQ ID NO: 3. However, assuming 100% sequence identity with nucleotides 1-1532, a polynucleotide sequence that is 2893 bp in length (i.e., sequence 3 in WO 0183746) has, at best, only 52.9% identity with nucleotides 1-1532 of SEQ ID NO: 3. Thus, the 2893 bp polynucleotide disclosed in Rosier-Montus is not an isolated polynucleotide that is at least 80% identical to nucleotides 1-1532 of SEQ ID NO: 3, as required by claim 7. In view of the differences between the 2893 bp sequence taught in Rosier-Montus and the claimed sequence, and given that the Rosier-Montus sequence does not teach each and every element as set forth in the claim, it does not anticipate claim 7.

Applicant respectfully requests withdrawal of the 35 U.S.C. § 102(e) rejections in view of the Rosier-Montus reference.

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Conclusion

In view of the above remarks, the application is considered to be in good and proper form for allowance and the Examiner is respectfully requested to pass this application to issue. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of this application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,
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